REMARKS

Claims 1-25 are pending in the instant application. Claims 1-25 have been rejected by the Examiner. The Applicant submits that claims 1-25 are in condition for allowance and requests reconsideration and withdrawal of the outstanding rejections. No new matter has been entered.

Claim Rejections Under - 35 USC §112

Claims 11-20 have been corrected in accordance with the Examiner's suggestions.

Claim Rejections Under - 35 USC §102

(A) *Claims 1, 2 and 9 have been rejected under 35 U.S.C. 102(b) with regard to U.S. Patent No. 4,779,616 to Johnson (hereinafter "Johnson").*

In relevant part, independent claim 1 requires "*an attaching member extending from the body for attaching the body on an exterior portion of the surgical instrument.*"

Referring to Johnson, item 10 (see FIGURE 1) is simply a suture retrieval device. While it is inserted through a cannula 18 in the body to grab a suture in the body, it does not teach an attaching member at all.

The Examiner would call item 12 an attaching member, but item 12 does not attach (grab in some way) to the device 18. Item 12 is just a handle for loop 14. Also, there is no teaching to attach the handle 12 to cannula 18 (the only disclosed other medical device).

In paragraph 1 of the Examiner's January 8, 2008 action, the Examiner indicates a belief that the handle 12 of Johnson is "capable" of attaching to the exterior portion of a surgical device and could thus read on independent claim 1. Even a cursory review of FIGURE 1 reveals that there is nothing extending from Johnson's item 12 that would be capable of grasping or otherwise attaching to an exterior portion of a separate surgical device.

Further, it is noted that the exterior portion of the surgical device is positively recited in the body of claim 1, and the surgical device is also positively recited in the preamble (Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251,

1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989)). See also *In re Stencel*, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987). (The claim at issue was directed to a driver for setting a joint of a threaded collar; however, the body of the claim did not directly include the structure of the collar as part of the claimed article. The examiner did not consider the preamble, which did set forth the structure of the collar, as limiting the claim. The court found that the collar structure could not be ignored. While the claim was not directly limited to the collar, the collar structure recited in the preamble did limit the structure of the driver. "[T]he framework - the teachings of the prior art - against which patentability is measured is not all drivers broadly, but drivers suitable for use in combination with this collar, for the claims are so limited." Id. at 1073, 828 F.2d at 754.).

Claim 1 thus positively calls out the suture loading assembly and the surgical device as distinct members, with the attaching member extending from the body of the suture loading assembly to an exterior portion of the surgical device.

In order to make out a prima facie case of obviousness, a proposed combination of prior art references must teach or suggest all of the limitations of the rejected claims. *In re Vaech*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991); *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970).

Because Johnson fails to teach all limitations of independent claim 1, the rejections of claim 1 and dependent claims 2 and 9 are in error. Reconsideration is respectfully requested.

(B) *Claims 1-5 and 9 have been rejected under 35 U.S.C. 102(b) with regard to U.S. Patent No. 4,917,082 to Grossi et al. (hereinafter "Grossi").*

As with Johnson, Grossi fails to teach all of the required limitations of the claims. In relevant part, Grossi requires "a flexible loop extending from a distal end of the body, wherein the flexible loop in a first position, is provided through an opening in the body of the surgical instrument, and in a second position is provided at least partially retracted from said opening, wherein in said second position, said suture material is at least partially provided within said surgical instrument opening."

It is immediately evident that Grossi does not teach a flexible loop. Grossi teaches an electrode device with a stiff electrode tip 22. Note Grossi, Column 4, lines 59-61, "The second conductor 48, for the cutting loop assembly, is generally comprised of tungsten wire, which is bent at suitable locations to form a portion of two arms 18, 20 and the electrode tip 22 connecting the two arms 18, 20 at the distal tip of the electrode assembly. Also note Column 4, lines 63-65, "Two inner sleeves 50, 52 are placed over the second conductor 48 to add rigidity or stiffness thereto..." Grossi clearly teaches a rigid structure configured to retain shape. Grossi is clearly inapposite to the claimed flexible loop configured to be provided through the distal tip of the surgical device. Because of the rigidity of Grossi, the disclosed Grossi device would not be able to transition between the claimed first position and the second, retracted position.

Because Grossi does not teach all of the required limitations of independent claim 1, the rejection is in error with regard to claims 1-5 and 9.

It is also noted that the Examiner contends the term "suture" does not lend any definition to the claims. However, the practical requirement of the claims by virtue of the suture recitation is that the loop must be flexible such that it can capture the suture. The term clearly supports and lends definable structure to the loop as well as to the recited first and second portions (i.e., the loop threaded through the opening in the surgical device and the loop retracted therethrough with suture captured therein (the rigid, stiffened Grossi would not be able to or be intended to function this way))(Any terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation. See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989)). See also *In re Stencel*, 828 F.2d 751, 4 USPQ2d 1071 (Fed. Cir. 1987) (The claim at issue was directed to a driver for setting a joint of a threaded collar; however, the body of the claim did not directly include the structure of the collar as part of the claimed article. The examiner did not consider the preamble, which did set forth the structure of the collar, as limiting the claim. The court found that the collar structure could not be ignored. While the claim was not directly limited to the collar, the collar structure recited in the preamble did limit the structure of the driver. "[T]he framework – the teachings of the prior art – against which patentability is measured is not all drivers broadly, but drivers suitable for use in combination with this collar, for the claims are so limited." *Id. at* 1073, 828 F.2d 754.).

For these additional reasons, the Examiner's rejections are in error. Reconsideration is respectfully requested.

(C) Claims 1-2 and5-9 have been rejected under 35 U.S.C. 102(b) with regard to U.S. Patent No. 5,501,692 to Riza (hereinafter "Riza").

Riza is similar to Johnson as a laparoscopic suture snare. Riza is penetrated into the body, a piston is pushed to extend the snare, and the piston is released to capture/draw in the snare and suture. Riza does not mount onto an exterior portion of a separate device.

In paragraph 1 of the Examiner's January 8, 2008 action, the Examiner treats Riza identically with Johnson. Riza teaches NO more than does Johnson (that is, NOWHERE does Riza teach anything close to an attaching member extending from the Riza device for attaching (or being capable of grabbing or attaching) to a separate device. That teaching or suggestion is simply lacking. Accordingly, the discussion above with regard to Johnson is incorporated herein by reference with regard to Riza.

The rejections with regard to Riza and claims 1-2 and 5-9 are thus in error, and reconsideration is respectfully requested.

(D) *Claims 1, 9, 11-13 and 20 have been rejected under 35 U.S.C. 102(b) with regard to U.S. Patent No. 5,935,149 to Elk (hereinafter "Elk").*

Elk does describe a suture loading component 400, but fails to teach the "attaching member extending from the body for attaching the body on an exterior portion of the elongated tubular portion of the suture securing instrument." The Elk device is best seen in FIGURE 12. The Examiner claims that the ring 402 attached to the suture loading wire meets the above cited limitation required by independent claims 1 and 11. However, if the body is the attaching wire 400, and the ring 402 is the attaching member, it is clear that the ring 402 in no way extends from the body 400 to the exterior portion of the elongated tubular portion (which would be item 360) for attachment thereto.

Indeed, Elk merely shows the state of the earlier "ripcord" style loader rather than the presently described improvement thereto, which mounts a suture loading assembly body onto the exterior portion of the surgical device. Because Elk fails to teach the above-cited limitations, the rejection is in error, and reconsideration is requested.

(E) Claims 1, 11-13, 18 and 19 have been rejected under 35 U.S.C. 102(b) with regard to U.S. Patent No. 5,520,702 to Sauer et al. (hereinafter "Sauer '702").

Sauer '702 teaches exactly the same prior art "ripcord" style suture loading as Elk. Accordingly, the discussion above with regard to Elk is incorporated by reference and applied to Sauer '702 herein.

Thus, for the same reasons as with Elk above, the rejection is in error. Reconsideration is respectfully requested.

It is also noted that the Examiner first indicated in paragraph 2 of the Examiner's January 8, 2008 action, that the Applicant's claim could be met/rendered obvious simply by attaching the ripcord ring of Sauer to the device body by "clipping them together with a third piece." This is neither taught nor suggested by Sauer '702. We again respectfully assert that the Examiner is impermissively using hindsight in an attempt to find the Applicant's claims using the prior art.

Sauer '702 operates by grasping the ring and 'pulling the ripcord' from the device. Ignoring (only for the moment) the fact that the Examiner has failed to cite a piece of prior art using such a clip on a ripcord-like ring for attaching the ring to the device body, Sauer would not benefit from such a clip. In the worst case, it would render Sauer '702 inoperable (hampering or preventing the ring from being pulled from the device). In the best case, it would be undesirable (hampering actuation of the clip, or adding an additional undesirable step (in a sterile, medical operation no less) and thus inconveniencing the physician.

There is no motivation to modify Sauer '702. For this additional reason, the Examiner's rejections are in error, and reconsideration is requested.

Claim Rejections Under - 35 USC §103

(F) Claim 10 has been rejected under 35 U.S.C. 103(a) with regard to Johnson.

The deficiencies of Johnson (the fact that Johnson completely fails to teach an attaching member as described by the claims) are detailed above. The above is thus incorporated by reference herein. Reconsideration is respectfully requested.

(G) Claims 16 and 17 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Sauer '702 in view of U.S. Patent No. 4,102,478 to Samoilov (hereinafter "Samoilov").

The deficiencies of Sauer '702 have been noted above and are incorporated by reference herein. Samoilov is simply a threader having a handle and similarly completely fails to teach the "attaching member extending from the body for attaching the body on an exterior portion of the elongated tubular portion of the suture securing instrument. Thus, Samoilov does not make up for the deficiencies of Sauer '702, and a prima facie case has still not been made out. Reconsideration is respectfully requested.

(H) Claims 14-15 and 21-25 have been rejected under 35 U.S.C. 103(a) with regard to Sauer '702 in view of U.S. Patent No. 5,643,289 to Sauer et al. (hereinafter "Sauer '289") and U.S. Patent No. 4,134,406 to Iglesias (hereinafter "Iglesias").

The deficiencies of Sauer '702 are detailed above and are incorporated herein by reference. Also the discussion above noting the lack of motivation to modify the "ripcord" type device of Sauer '702 (and Sauer '289) is incorporated by reference herein.

Effectively, the Examiner primarily relies on a general teaching (e.g., from Igleseas) that one surgical device may be mounted onto another (Igleseas merely teaches a cutting loop mounted within a channel of a resectoscope). The Examiner then coupled that general teaching with the statement in Sauer '289 that 'the threading tool may be modified so that the threading can be accomplished intracorporeally.' With those two premises, the Examiner concluded that it would be obvious to provide the suture loading body provided as engaged to the body of the separate surgical device.

It is not disputed that some medical devices are a composite of two attached and distinguishable elements. This does not, however, mean that whenever a medical device is engineered to directly engage another (this engineering construction being new in the relevant device art), that it CANNOT be patentable. Indeed, in the present case, going from a 'ripcord' type configuration to a more integrated engaged configuration required engineering and provided great benefits (as noted above, the attaching member of the present ferrule loader permits a more secure grip, eliminates the need for a bulky ring grip and reduces the worry that the distal suture loading ring will slip out). This configuration should not be dismissed SIMPLY on the premise that creating a suture loading body that attaches to the surgical device is obvious simply because other people have combined/attached two objects in the past.

Further, the Examiner calls out the teaching of Sauer '289, (to quote the Examiner): 'the threading tool may be modified so that the threading can be accomplished intracorporeally.' The Examiner indicates that this means construction of a body that attaches to the crimper. However, this does not follow. The most obvious meaning is that the 'ripcord' just extends further through the crimper bore. Thus, Sauer '289 would have the same configuration outside the device (i.e., no body attached to the crimping device. To suggest otherwise is to read the applicant's teachings (impermissively using hindsight) into the general comment made by Sauer '289 (which does not mention AT ALL engineering and attaching a suture loader body to the crimping device). Sauer '289 just doesn't provide the motivational link that the Examiner is looking for.

The prior art simply does not teach engineering a suture loader body and attaching it to the surgical device. Similarly, the Examiner cannot say that the engineered combination is obvious because of devices have generally been combined in the past. The present invention is an advancement over the previous suture loaders precisely because a proximal body was engineered to attach to the surgical device rather than relying on a 'rip cord' handle. While claims 21-25 specifically call out a suture securing member having a ferrule through which the suture is loaded, the independent claims each recite the attachment of the suture loader body to the body of the surgical device (and have been amended to specifically clarify that the device is to load suture through an opening in the surgical device).

The simple fact is that both Sauer '702 and Sauer '289 utterly fail to teach a suture loading assembly body attached to the exterior surface of a suturing device (just the 'ripcord' ring

attached to the retrieval wire that is threaded through the ferrule). ***The Examiner has failed to cite any kind of device with a suture loading assembly body that has an attaching member extending to attach to the exterior of a surgical device.*** Just because Iglesias shows one medical device (not even a suturing device) mounted on another (also not a suturing device or related thereto), does not provide the proper motivation to eliminate the ring of Sauer and create a body with attachment portions extending from the body to the device of the suture crimping device (This is exactly the kind of impermissible hindsight construction that the law warns against).

Reconsideration and allowance of all the rejections is requested in light of the above.

CONCLUSION

It is believed that the foregoing amendments and remarks fully comply with the Office Action and that the claims herein should now be allowable to Applicants. Accordingly, reconsideration and allowance is requested. It is submitted that the foregoing amendments and remarks should render the case in condition for allowance.

Accordingly, as the cited references neither anticipate nor render obvious that which the applicant deems to be the invention, it is respectfully requested that the claims be passed to issue.

If there are any charges with respect to this Amendment or otherwise, please charge them to Deposit Account No. 06-1130. This is a general authorization to charge fees to the aforementioned Deposit Account.

Respectfully submitted,

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